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| 10/535,129  | 05/13/2005  | Tetsuya Sakata       | 10921.319USWO       | 3606             |
| 52835 7590 08/13/2009<br>HAMRE, SCHUMANN, MUELLER & LARSON, P.C.<br>P.O. BOX 2902<br>MINNEAPOLIS, MN 55402-0902 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| SZPIRA, JULIE ANN   |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 3731  |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/535,129

**Applicant(s)**

SAKATA, TETSUYA

**Examiner**

JULIE A. SZPIRA

**Art Unit**

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Receipt is acknowledged of applicant's amendment filed 4/28/2009. Claims 1-15 are pending and an action on the merits is as follows.

#### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

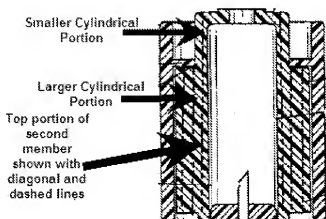
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-3 and 6** are rejected under 35 U.S.C. 102(b) as being anticipated by **Ramel (US 5,540,709)**.

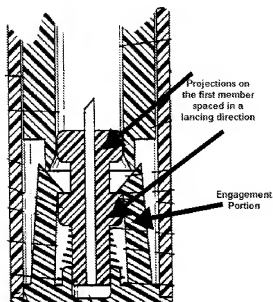
**Regarding claim 1**, Ramel discloses a lancet to be attached to a lancing apparatus for moving a lancing element (needle, 4) in a lancing direction from a standby position toward a lance position, the lancet comprising a first member (2) including a lancing element (4) and a second member (40, 18) movable relative to the first member (column 3, lines 27-33) and including a smaller cylindrical portion and a larger cylindrical portion, the smaller cylindrical portion being configured to accommodate a tip of the lancing element, the larger cylindrical portion being formed integral with the smaller cylindrical portion and greater in outer diameter than the smaller cylindrical portion; wherein when a load greater than a predetermined value is applied in a direction to cause the first member and the second member to approach each other, the first member is brought closer to the second member so that the tip of the lancing element is capable of projecting from the smaller cylindrical portion of the second member (Figure

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7), whereas when the first member is brought away from the second member, the tip of the lancing element is accommodated in the second member without projecting from the smaller cylindrical portion of the second member (Figure 8).



**Regarding claims 2 and 3,** Ramel discloses the fixer comprises a pair of projections which project at the first member in a direction crossing the lancing direction and which are spaced from each other in the lancing direction (see figure below) and an engagement portion (18) provided at the second member to be held between the paired projections.



Regarding claim 6, Ramel discloses the projections being on the shaft and the shaft being circular (annular), therefore the projections would be annular as well (column 4, lines 56-58).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. **Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Ramel (US 5,540,709)**.

**Regarding Claim 4**, Ramel discloses the invention substantially as claimed above, but fails to disclose the second projection that projects more than the first projection.

It would have been an obvious matter of design choice to make one projection larger than the other, since it has been held that a change in size is a matter of design choice and is generally recognized to be within the level of ordinary skill in the art. In re Rose, 105 USPQ 237.

6. **Claims 5 and 7-9** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Ramel (US 5,540,709)** in view of **Searle et al (US 2002/0087180 A1)**.

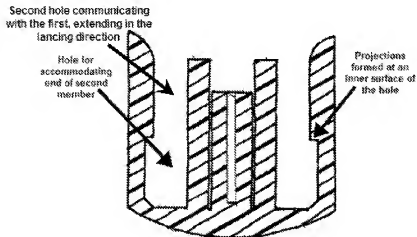
**Regarding claim 5**, Ramel discloses the invention substantially as claimed above, but fails to disclose the second projection serving as a stopper.

However, Searle et al. teaches a first member with a projection (formed by undercuts, 32) that serves as a stopper to engage with the engagement portion (38) of the second member (16) (paragraph 23, lines 3-5).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a projection to engage the second member to the first member when the second member is moving in a lancing direction to prevent the second member from becoming detached (paragraph 28, lines 3-7)

**Regarding claims 7 and 9,** Ramel discloses the invention substantially as claimed above, but fails to disclose the first member including a hole, and further comprising an additional hole communicating with the first hole.

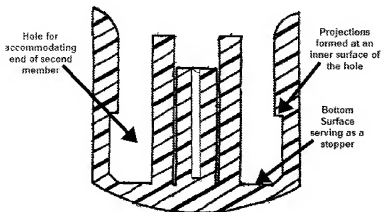
However, Searle et al. teaches a hole in the first member for accommodating an end of the second member and allowing movement of the second member; wherein the projections are formed at an inner surface of the hole (See Figure below), and the device is capable of applying force to the second member via the additional hole..



It would have been obvious to one having ordinary skill in the art at the time the invention was made to accommodate the second member in a hole in the first member to allow for the second member to be slidably coupled to the first member (paragraph 7, lines 3-6).

**Regarding claim 8,** Ramel discloses the invention substantially as claimed above, but fails to disclose the hole having a bottom surface serving as a stopper.

However, Searle et al. teaches a hole having a bottom surface serving as a stopper for controlling the movement of the second member (see Figure below; Figure 8)



It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the bottom surface of the hole be a stopper to allow the lancet to reach a fully extended position without having the needle puncture the patient too deeply (paragraph 26, lines 17-20)

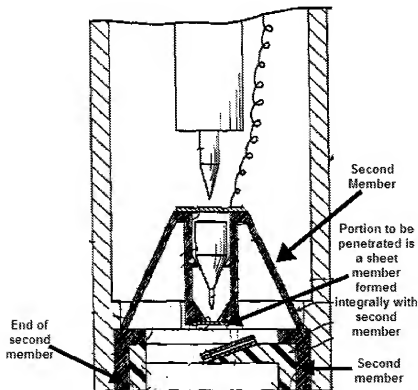
7. **Claims 10-13** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Ramel (US 5,540,709)** in view of **Hamamoto (US 7,250,056)**.

**Regarding claims 10-13**, Ramel discloses the invention substantially as claimed above, but fails to disclose the tip of the lancing element in a hermetically sealed state formed by an integrally formed sheet member attached to the second member.

However, Hamamoto teaches the lancing element (47) accommodated in a hermetically sealed state, and includes a portion (44b) to be penetrated by the tip of the lancing element (column 8, lines 56-60; Figures 5A-5C). The portion to be penetrated is integrally formed (welded) with the second member and provided by a sheet member



(thin metal film or resin sheet) (column 4, lines 5-9), and wherein a portion to be penetrated is provided at a position retreating in a direction opposite to the lancing direction (Figure 3). Furthermore, the portion to be penetrated is set back from the end of the second member in a direction opposite of the lancing direction (see Figure below)

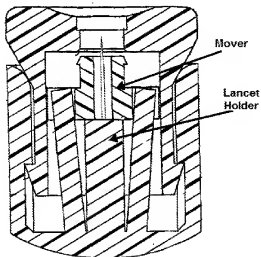


It would have been obvious to one having ordinary skill in the art at the time the invention was made to hermetically seal the lancing element to prevent deterioration and contamination of the lancet (paragraph 88, lines 3-10).

8. **Claims 14 and 15** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Searle et al (US 2002/0087180 A1)** in view of **Ramel (US 5,540,709)**.

**Regarding claim 14**, Searle et al. discloses a lancing apparatus which is used by mounting a lancet and which moves the lancet in a lancing direction from a standby

position toward a lance position; the lancet comprising a first member (12) including a lancing element (14) and a second member (16) for accommodating a tip of the lancing element, the first member and the second member being movable relative to each other, wherein when a load greater than a predetermined value is applied in a direction to cause the first member and the second member to approach each other, the first member is brought closer to the second member so that the tip of the lancing element is capable of projecting from the lancing element (paragraph 26, all lines), whereas when the first member is brought away from the second member, the tip of the lancing element is accommodated in the second member without projecting from the second member (Figure 9), the lancing apparatus comprising: a lancet holder (See Below) for holding the lancet, the lancet holder being movable in the lancing direction; and a mover (18) which is movable relative to the lancet holder for moving the second member relative to the first member in the lancing direction, and for causing the tip of the lancing element projecting from the second member to be brought into the second member to be accommodated therein (Figures 8 & 9; See Figure Below).



Searle et al. fails to disclose the second member having a smaller cylindrical portion and a larger cylindrical portion, the smaller cylindrical portion being configured to accommodate a tip of the lancing element, the larger cylindrical portion being formed integral with the smaller cylindrical portion and greater in outer diameter than the smaller cylindrical portion.

However Ramel et al. teaches a smaller cylindrical portion and a larger cylindrical portion, the smaller cylindrical portion being configured to accommodate a tip of the lancing element, the larger cylindrical portion being formed integral with the smaller cylindrical portion and greater in outer diameter than the smaller cylindrical portion (See Figure Below).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the second member have a smaller cylindrical portion to aid in aligning and centering the lancet to ensure accuracy of the lancet placement during deployment of the device (Ramel, column 2, lines 58-64). The smaller cylindrical portion will further aid in ensuring the lancet is focused in on its lancing target.

**Regarding claim 15**, Searle et al. discloses the mover moved in the lancing direction to engage with the second member and moves the second member relative to the first member in the lancing direction (paragraph 26, lines 7-22) but fails to disclose thereafter pushing the lancet out of the lancet holder.

However, Ramel et al. teaches a lancet holder (clips and arms; 20 and 18), which the lancet is pushed out of during use of the device (column 3, lines 26-32).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to push the lancet out of the holder to allow for the used lancet to be disposed of properly.

***Response to Arguments***

9. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE A. SZPIRA whose telephone number is (571)

270-3866. The examiner can normally be reached on Monday-Thursday 9 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie A Szpiral/  
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731  
8/12/09